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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,794	07/28/2003	Robert I. Rudko	LE-205J	4536
7590 04/13/2005			EXAMINER	
Iandiorio & Teska 260 Bear Hill Road Waltham, MA 02451-1018			STRAIGHTIFF, MICHAEL PAUL	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 04/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/628,794

Applicant(s)

RUDKO ET AL.

Examiner

Michael P. Straighttiff

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16-18 is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/23/04, 5/3/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS - 8/2/04, 1/26/05</u> . |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:
 - a. Page 4, Line 12 of the specification makes reference to U.S. Patent No. "6,105,515" and should instead refer to U.S. Patent No. --6,106,515--Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-5 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication No. US 2002/0045848 to Jaafar et al.
 - a. In regard to Claim 1, Jaafar et al. disclose "[A] endovascular tissue removal device: comprising a lumen including a distal steerable tip portion extending from a joint portion" (See Jaafar et al., Figure 1, References 16 "lumen" and 14 and 32 "distal steerable tip portion"), a "registration means for holding the joint portion fixed in place in the vasculature" (See Jaafar et al., Figure 1, Reference 21), and "a source of ablation energy in communication with the lumen" (See Jaafar et al., Figure 1, Reference 12).

- b. In regard to Claim 2, Jaafar et al. further disclose "in which the registration means includes an inflatable balloon about the joint portion" (See Jaafar et al., Figure 1, Reference 21; See also Paragraph [0026, Lines 11-14).
 - c. In regard to Claim 3, Jaafar et al. further disclose "in which the source of ablation energy is a laser" (See Jaafar et al., Figure 1, Reference 12).
 - d. In regard to Claim 4, Jaafar et al. further disclose "in which the distal steerable tip portion includes a deflectable tip catheter" (See Jaafar et al., Paragraph [0030]).
 - e. In regard to Claim 5, Jaafar et al. further disclose "in which there is an optical fiber inside the deflectable tip catheter and connected to the laser" (See Jaafar et al., Paragraph [0027, Lines 1-2).
 - f. In regard to Claim 10, see Claims 1 and 2 Rejections.
 - g. In regard to Claim 11, see Claims 1 and 5 Rejections.
 - h. In regard to Claim 12, see Claims 1 and 4 Rejections.
 - i. In regard to Claim 13, see Claims 1-5 Rejections.
4. Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,366,490 to Edwards et al.
- a. In regard to Claim 1, Edwards et al. disclose "An endovascular tissue removal device comprising: a lumen including a distal steerable tip portion extending from a joint portion" (See Edwards et al., Figure 2, Reference 14 "lumen", Reference 34 "joint portion"), a "registration means for holding the joint

portion fixed in place in the vasculature" (See Edwards et al., Figure 2, Reference 32), and "a source of ablation energy in communication with the lumen whereby tissue can be resected by ablation energy as the tip portion is steered within the vasculature" (See Edwards et al., Figure 12, Reference 150).

b. In regard to Claim 2, Edwards et al. further disclose "in which the registration means includes an inflatable balloon about the joint portion" (See Edwards et al., Figure 2, Reference 32; See also Column 6, Line 68 – Column 7, Line 4).

c. In regard to Claim 3, Edwards et al. further disclose "in which the source of ablation energy is a laser" (See Edwards et al., Column 5, Lines 21-24).

d. In regard to Claim 4, Edwards et al. further disclose "in which the distal steerable tip portion includes a deflectable tip catheter" (See Edwards et al., Figure 2, Reference 14).

e. In regard to Claim 5, Edwards et al. further disclose "in which there is an optical fiber inside the deflectable tip catheter and connected to the laser" (See Edwards et al., Column 5, Lines 21-24).

f. In regard to Claim 6, Edwards et al. further disclose "an expandable barrier" (See Edwards et al., Figure 2, Reference 30).

g. In regard to Claim 7, Edwards et al. further disclose an "inflatable... expandable mechanism" (See Edwards et al., Figure 2, Reference 30; See also Column 6, Line 68 – Column 7, Line 4). The intended use/functional language "on the ventricular side of the valve for supporting the leaflets of the valve"

carries limited patentable weight in the absence of any distinguishing structure.

Edwards et al.'s "inflatable expandable mechanism" clearly discloses the structure and is considered inherently capable of performing the intended use.

h. In regard to Claim 8, Edwards et al. further disclose "an absorptive surface on the expandable mechanism for absorbing energy". As broadly as claimed, the surface of the balloon (See Edwards et al., Figure 2, Reference 30) is considered by the Examiner to be "an absorptive surface".

i. In regard to Claim 9, Edwards et al. disclose "in which the expandable mechanism is a balloon" (See Edwards et al., Column 6, Line 68 – Column 7, Line 4).

j. In regard to Claim 10, see Claims 1 and 2 Rejections.

k. In regard to Claim 11, see Claims 1 and 5 Rejections.

l. In regard to Claim 12, see Claims 1 and 4 Rejections.

m. In regard to Claim 13, see Claims 1-5 Rejections.

n. In regard to Claim 14, see Claim 6 Rejection.

o. In regard to Claim 15, see Claims 13 and 14 Rejections.

5. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,545,214 to Stevens.

a. In regard to Claim 16, Stevens discloses "A method of resecting a valve, the method comprising: endovascularly introducing a lumen with a distal steerable tip portion to a position proximate a valve to be resected" (See

Stevens, Column 3, Lines 48-52), "registering the lumen in place in the vasculature" (See Stevens, Column 3, Lines 52-56), "directing ablation energy through the lumen", and "steering the distal tip portion to resect the valve" (See Stevens, Column 3, Lines 56-66).

Allowable Subject Matter

6. Claim 17 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
7. Claim 18 is allowed.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Straightiff whose telephone number is (571) 272-4774. The examiner can normally be reached on Monday through Friday 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700

Art Unit: 3739

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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